IN THE UNITED STATE DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

PETER G. KRAUSS, Plaintiff, v. C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., Defendants.	Case No.: **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL**

COMES NOW Plaintiff, PETER G. KRAUSS, by and through his undersigned attorneys, and alleges as follows:

INTRODUCTION

1. This case involves the implantation of a device called an inferior vena cava filter that is intended to be placed into the vessel leading to the heart in order to filter all blood clots from being transported in the blood to the lungs, the heart and the brain.

2. This is a civil action to secure redress from C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC. (collectively "Bard" or "Defendants") for damages suffered by Plaintiff as a result of Defendants' defective Bard-branded inferior vena cava ("IVC") filter marketed as the Bard Recovery IVC Filter (the "Device").

3. Plaintiff brings this case for serious personal injuries that Plaintiff suffered as result of the failure of the surgically implanted defective and dangerous Device, which was researched, developed, manufactured, marketed sold and distributed by Defendants.

4. The Device's failure has caused Plaintiff to suffer grievous ongoing physical, emotional, and economic losses, all of which will continue far into the future.

5. Prior to Plaintiff's implantation of the Device, Defendants knew and should have known that the Device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

a. Defendants failed to conduct appropriate clinical testing, such as animal studies, to determine how the Device would function once permanently implanted in the human body.

b. Defendants knew and/or should have known that the Device and their other IVC filters had a high rate of perforation of tissues, fractures of the Device, migration from the implantation site, and excessive tilting within the vena cava once implanted.

c. Defendants knew and/or should have known that such failures exposed patients to the increased risk of serious injuries including: death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforation of tissue, vessels and organs; increase risks of developing DVTs and the inability to remove the Device.

d. Defendants knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the Device.

e. Defendants knew or should have known that these risks were and are substantially higher than risks posed by other IVC filters.

f. Defendants knew and/or should have known that filters such as the Device are used to treat conditions which Defendants did not explicitly intend and which resulted in the Device not performing as safely as the ordinary consumer would expect.

6. Despite knowledge of these risks, Defendants misrepresented, omitted, and/or failed to provide adequate warnings of these and other risks posed by the Device.

7. Defendants failed to recall this dangerous Device at many opportunities, when Bard knew and had reason to know that the Device was unnecessarily dangerous for its intended purpose.

PARTIES

Plaintiff

8. Plaintiff Peter G. Krauss ("Plaintiff") is a natural person who is a citizen of the State of Connecticut residing in Middlesex County.

Defendants

9. Defendant C.R. Bard, Inc. ("C.R. Bard") is a corporation authorized to do business in the State of Rhode Island. Defendant C.R. Bard regularly sells and markets its medical devices in the State of Rhode Island. Defendant C.R. Bard is organized and existing by virtue of the laws of the State of Delaware and has its principal place of business in Murray Hill, New Jersey.

10. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly-owned subsidiary corporation of C.R. Bard. Defendant BPV is a corporation authorized to do business in the State of Rhode Island. Defendant BPV regularly markets and sells its medical devices in the State of Rhode Island. Defendant BPV is organized and existing under the laws of the State of Arizona and has its principal place of business in Tempe, Arizona.

11. At all relevant times, Defendants engaged in the research, design, assembly, manufacture, testing, quality control, sale, advertising, marketing, distribution Bard IVC filters and their appurtenances and component parts in the U.S. and especially in Rhode Island.

12. Defendants, directly and/or through their agents, marketed and sold the Bard Recovery IVC Filter, which is the subject of this lawsuit ("the Device"), other IVC filters, and other medical products in the State of Rhode Island. Defendants derived substantial revenue from marketing and selling these products in the State of Rhode Island. Defendants expected, or should have expected, that their business activities might subject them to legal action in the State of Rhode Island.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1332(a)(1) because Plaintiff and Defendants are citizens of different states, the amount in controversy exceeds the sum or value of seventy-five thousand dollars ($75,000.00) exclusive of interest and costs, and there is complete diversity of citizenship between each Plaintiff and Defendant.

14. This Court has personal jurisdiction under 28 U.S.C. § 1391, as Defendants regularly conduct business in the State of Rhode Island. Venue is appropriate in this District as the Defendants are present and doing continuous and systemic business within the State of Rhode Island.

ALLEGATIONS

A. IVC FILTERS

15. Inferior vena cava ("IVC") filters first came onto the medical market in the 1960's. Since that time, medical device manufacturers have introduced several different designs of IVC filters.

16. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters are designed to be implanted, either permanently or temporarily, in the inferior vena cava.

17. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called "deep vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered "pulmonary emboli," or "PE." Pulmonary emboli are potentially fatal.

18. People at risk for DVT/PEs can undergo medical treatment to manage the risk. For example, a doctor may prescribe anti-clotting medications such as Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. For those who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

19. The first IVC filters marketed were permanent filters. These devices were designed to remain in the patient's IVC permanently. The medical literature refers to several studies that present long-term follow-up data (of up to 20 years and longer), that supports the use and efficacy of certain permanent filters.

20. Beginning in 2003, Defendants began marketing what are known as optional or retrievable filters. These filters are designed so that they can be surgically removed from the patient after the risk of blood clots has diminished.

21. These devices have only been approved by the FDA to prevent recurrent pulmonary embolism where anticoagulant therapies are contraindicated or have failed. Thus, any use other

than in a patient with a history of pulmonary embolism who failed to control their blood clots with pharmaceutical anticoagulants is not an FDA approved and indicated uses, therefore it is an off-label use.

B. THE RECOVERY FILTER

1. Simon Nitinol Filter and Bard's Reach for Greater Market Share

22. Bard has distributed and marketed the Simon Nitinol[1] Filter in the United States since 1992. The Simon Nitinol Filter is a permanent IVC filter, which is substantially safer than Bard's optional filters and is still sold by Bard today. Bard modified the design of the Simon Nitinol Filter in order to make a device that was supposed to be equally safe to leave in permanently, or to retrieve once the risk of pulmonary embolism had passed. The modified device was ultimately marketed as the Recovery Filter System (the "Recovery Filter").

23. Bard's stated purpose in designing the Recovery Filter was to increase the overall size of the market for these devices through off-label promotion and to increase Bard's percentage of that market. Specifically, Bard marketed the device for patients who were at risk for DVTs and PEs, but who had not actually had a documented pulmonary embolism as required by the FDA label. This new market included patients who were immobilized for periods of time after surgical procedures, *e.g.*, orthopedic patients, bariatric patients, and cancer patients.

24. Prior to the FDA's clearance of the Recovery Filter, Bard was losing market share in an IVC Filter market that was reported to be worth $100,000,000.00 in sales. In July 2001, Bard's overall market share was 16-17%; by March 2003, it was down to 11-12%.

25. Bard's marketing manager explained Bard's marketing plan for the Recovery Filter in a March 28, 2003 Market Appraisal Memorandum. She wrote, "Users can be swayed by ease

[1] Nitinol derives its name from its component parts and place of discovery: **N**ickel **Ti**tanium **N**aval **O**rdnance **L**aboratory.

of use, low profile and aggressive marketing even in the absence of solid clinical history and in spite of negative clinical experience."

2. FDA Clearance

26. In 2002, Bard and BPV submitted a "me too" application to the FDA that Bard and BPV be permitted to market the Recovery Filter System for the prevention of recurrent pulmonary emboli, claiming it was substantially similar in safety, efficacy, design, and materials as the Simon Nitinol filter. On November 27, 2002, the FDA cleared the Bard Recovery Filter for sale and use in the prevention of recurrent pulmonary embolism via permanent placement in the inferior vena cava.[2]

27. In April 2003, Bard submitted a notification of intent to market and sell the Recovery Filter for the additional intended use of optional retrieval. Bard received FDA clearance to begin marketing the Recovery Filter as both a permanent and retrievable filter on or about July 25, 2003.

28. Ultimately, Bard's plan to promote its retrievable devices for off-label uses and for unproven benefits succeeded. By 2009, the overall market for IVC filters had tripled, and Bard's percentage share of that market increased from 11-12% to 42%.

29. Among Bard's marketing claims to physicians was that the Recovery Filter was safer than all previously available filters, including the Simon Nitinol Filter. This claim was false.

[2] Bard and BPV submitted the notification under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976, 21 U.S.C. § 321 *et seq*. The 510(k) review process requires any entity engaged in the design, manufacture, distribution or marketing of a device intended for human use to notify the FDA 90 days before it intends to market the device and to establish that the device is substantially equivalent to a legally marketed predicate device. 21 C.F.R. §§ 807.81, 807.92(a)(3). Substantial equivalence means that the new device has the same intended use and technological characteristics as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval process

3. The Design of the Recovery Filter

30. The Recovery Filter is cone-shaped, consisting of two (2) levels of six (6) radially distributed NITINOL struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots. There are six short struts, commonly referred to as the arms, and six long struts, commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top/apex of the device. According to the Patent filed for this device, the short struts are primarily for "centering" or "positioning" within the vena cava, and the long struts with attached hooks are designed primarily to prevent the device from migrating from "normal respiratory movement" or even massive pulmonary emboli.

31. The Recovery filter is inserted percutaneously by a deployment catheter that is guided by a physician through a blood vessel into the inferior vena cava. The Recovery Filter is designed to be retrieved in a similar fashion.

32. The Recovery Filter included several design changes from the Simon Nitinol Filter. These include, but are not limited to, the following:

a. decreasing the leg span of the device;

b. decreasing the hook diameter of each hook on the leg struts;

c. decreasing the radial force of the struts; and

d. changing the closed petal arm strut design to an open arm strut design.

4. Bard's Design Efforts Were Inadequate

33. Each of Bard's design changes had the unintended consequence of substantially reducing the Recovery Filter's stability, *i.e.*, increasing the likelihood that the filter would move, tilt, migrate completely out of the area of placement, and lack structural integrity, increase its propensity to perforate the vena cava and let more clots go by it..

34. However, because Bard failed to conduct adequate testing and research, Defendants failed to realize that these design changes would result in the device not being reasonably safe for user needs.

35. In a 2009 Bard IVC Filter franchise review, Bard's Filter Franchise Team described Bard's weaknesses as follows:

a. Lack of thorough understanding dynamics of caval anatomy – impacting testing methods;

b. A historical reactive/evolution design mindset;

c. Product complications – forcing focus on reactive designing;

d. Limited understanding of user needs.

36. Due to Bard's lack of understanding of caval anatomy and the forces the device would be exposed to once implanted, Bard set design specifications that were not clinically relevant and did not account for the forces these devices would actually see when implanted in the human body. For instance, Bard's decision to set the minimum safety standard for migration resistance at 50 mmHg[3] reflected a complete lack of understanding of the forces this device could be exposed to once implanted.

37. Bard also failed to test the device under reasonably foreseeable conditions that the device would be exposed to when used in an intended and expected manner. Among other things, Bard knew that these devices could be placed in appropriately sized vena cavas that subsequently expanded beyond 28 mm in diameter. Bard knew that this expansion of the vena cava could decrease migration resistance if the device was challenged by a clot, and could lead to migration if the vena cava expanded beyond the leg span of the filter, such that the hooks were no longer in

[3] "mmHg" refers to a millimeter of mercury and is a unit of pressure.

touch with the vena cava walls. Yet Bard chose not to test the device to simulate how it would perform if caval distension (expansion) were to occur. Bard also failed to test the device to determine how its stability and structural integrity would perform if the device tilted, fractured, or perforated the vena cava.

5. Pre-Market Expectations

38. Prior to introducing the Recovery Filter and later the G2 and Eclipse Filters to market, Bard and consumers expected that a properly placed filter would remain stable, maintain structural integrity, and would not perforate the vena cava when used in a reasonably foreseeable manner. Bard's internal documents reflect these expectations:

a. Bard filed patents for its retrievable filters, which state, "An elastic hook is formed on the free end of an appendage to pierce the vessel wall and insure that the filter does not migrate in response to normal respiratory functions or in the event of a massive pulmonary embolism."

b. Bard's Product Performance Specifications for its retrievable filters provide specifications that are to ensure "user needs," which are that the devices must not migrate, fracture, or perforate the vena cava.

c. Bard's premarket testing, which failed to account for real world conditions, predicted that there would be no fractures, migration, or perforation failures.

d. Bard's pre-market design and testing documents state that if a clot challenges a filter, "pressure below the filter increases significantly and tends to drive the filter toward the heart," and that "the device must not migrate in response to such a challenge."

e. In a June 2004 Health Hazard Evaluation, Bard's Medical Director stated that clot-induced migrations are a malfunction of the device and a failure to carry out its intended function.

f. Bard's own quality engineers working on the retrievable filter projects admitted that if one of its filters is driven into the heart by a clot challenge, then the device failed to perform as intended.

g. In 2004, Bard conducted a physician focus group regarding what were the expected complications from IVC filters. The physicians reported that an IVC Filter must not migrate no matter how big a clot is.

h. Bard also marketed its retrievable filters as being "self-centering," meaning that they would not tilt or migrate from their placement in the vena cava.

6. Bard's Post-Market Surveillance Revealed the Recovery Filter Did Not Perform as Expected

39. Once the Recovery Filter was released to market, there were reported complaints, Bard's own investigations, and epidemiological studies that demonstrated that the design changes made from the Simon Nitinol Filter to its Recovery Filter had substantially reduced the stability, structural integrity, and perforation resistance of the device.

40. Even when properly placed, the Recovery Filter had an increased propensity to move, fracture, and/or perforate the vena cava when exposed to normal and expected *in vivo* (within the body) forces.

41. When fracture and migration failures occur, shards of the device or the entire device can travel to the heart, where they can cause cardiac tamponade (pressure caused by a collection of blood in the area around the heart), perforation of the atrial wall, perforation of vessels, myocardial infarction, and/or death. These fractured shards may also become embedded in tissue

or migrate to other organ systems and vasculature, such as the renal veins and heart and lungs, rendering them too dangerous to remove. When tilting, penetrating and perforating the vena cava walls occurs, the device can perforate nearby organs and vessels such as the aorta, duodenum, small bowel, and ureter, which may lead to hemorrhage, retroperitoneal hematomas, small bowel obstructions, extended periods of severe pain, and or/death. Further, given the risks of injury in attempting to remove devices that have penetrated or perforated the vena cava, the device may not be removable or may require complex and dangerous open vascular surgical removal. Moreover, Bard was aware that these failures and resulting injuries were far more likely to occur with the Recovery Filter versus other available IVC Filters. For instance:

a. On April 23, 2004, Bard's Corporate VP of Quality Assurance sent an email noting that the Recovery Filter's reported failure rates "did not look good compared to permanent filters" and promised to remove the filter from the market if its reported death rate became "significantly greater than the rest of the pack."

b. Multiple studies reported Bard's Recovery Filter to have a fracture and migration rate ranging from 21% to 31.7%.

c. In February 2004, Bard's Marketing Manager, Janet Hudnall, sent an email admitting that the Recovery Filter was being reported to have tilted at significantly high rate even though it was initially properly placed. She requested that this high rate of failure be downplayed to consumers.

d. In June 2004, Bard's divisional head of Quality Assurance, Doug Uelmen, admitted: "Bard has been in the permanent filter market for 10 years (SNF). We have had a great deal of experience with a traditional patient base, experiencing a very low and unremarkable

adverse event rate. We have now moved into the optional filter market with RNF and have experienced increased failures."

e. By July 2004, Bard was aware that the Recovery Filter had a reported fracture rate that was ***28 times*** higher than all other available IVC Filters.

f. In December 2004, Bard performed a risk assessment of the Recovery Filter, which analyzed reported failure rates. Bard concluded: "Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rate for all other filters. These differences were all statistically significant. Recovery's reporting rates for all adverse events, filter fracture, filter migration, and filter migration deaths were found to be significantly higher than those for other removable filters." Dr. Ciavarella, Bard's Medical Director, concluded that this risk (substantially higher reported failure rates) was not known or obvious to consumers, and that Bard should consider providing a warning regarding the reported increased failure rate.

g. By December 2004, according to Bard's own policy and procedures for when devices should be recalled, the Recovery filter was considered unreasonably dangerous for human health and required product correction and recall. But the Bard Defendants did nothing.

42. The Adverse Event Reports (AERs) associated with IVC filter devices demonstrate that certain Bard IVC filters are far more prone to device failure than are other similar devices.

43. A review of the FDA MAUDE database from the years 2004 through 2008, demonstrates that Bard's IVC filters are responsible for the following percentages of all AERs:

a. 50% of all adverse events;

b. 64% of all occurrences of migration of the device;

c. 69% of all occurrences of vena cava wall perforation; and

d. 70% of all occurrences of filter fracture.

44. These failures are attributable, in part, to the fact that the Recovery Filter was not designed to be able to withstand normal anatomical and physiological loading cycles.

45. In addition to design defects, the Recovery Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the absence of electropolishing and the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings compromises the structural integrity of the device while *in vivo*. In particular, the Recovery Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. The Recovery Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to failure.

7. Bard Engaged in a Design Review Regarding Migration Failures of the Recovery IVC Filter.

46. In late 2003, as migrations failures for the Recovery Filter continued to mount, Bard convened a group to reexamine the adequacy of the design of the Recovery Filter as it relates to its ability to remain stable after implantation. The group established a number of action items, including an investigation into what the minimum migration resistance specification of 50 mmHg had been based on comparison testing of the migration resistance of the Recovery Filter to other available filters, and comparing the radial force difference between the range of available devices.

47. This design review revealed that the minimum safety migration resistance specification was unsupported and had been set artificially low. Bard developed this critical safety standard based on undocumented informal estimates, obtained from then-unidentified physicians,

that the greatest pressure below a filter that could be seen in the vena cava was 35 mmHg. Bard then tested the device in three (3) sheep and claimed that the test results confirmed that 35 mmHg was the highest pressure that could ever be seen in the vena cava under worst case conditions. However, the test results from the sheep show pressure levels well above 50 mmHg, which Bard completely ignored.

48. Further, Bard's investigation concluded that multiple properly placed Recovery Filters migrated and caused deaths because the filters lacked adequate strength to resist clot challenges and/or lacked an adequate margin of safety to accommodate post-placement distention of the vena cava. This further confirmed that the safety specification of 50 mmHg inadequate and that Bard's testing, which predicted no migration failures, did not accurately reflect real world conditions.

49. As part of this design review in early 2004, Bard also spoke with its two longtime physician consultants, Drs. Venbrux and Kaufman. The doctors warned Bard that their input on the migration resistance specification had just been an "estimate" and that Bard needed to consider revising the migration resistance specification from 50 mmHg to 140 mmHg. They further warned Bard that the Recovery Filter was a "wimpy" filter and its radial force also needed to be increased to ensure stability.

50. The design review also revealed that the Recovery Filter had migration resistance values that were far below most other filters, including the Simon Nitinol Filter. Bard's internal records reveal that this was a known contributing factor to the Bard anchoring mechanism's failure.

51. Bard knew that caval distension (expansion of the vena cava diameter beyond the size at placement) could occur from multiple factors. These factors included: anesthesia, hydration following medical procedures such as bariatric procedures, exertion from exercise, coughing, and

straining during bowel movements. However, Bard to date has failed to make any efforts to determine the size of vena cava distension that can occur as a result of the tipping, tilting or migration of the filters.

8. Bard Investigated the Cause of the Fractures.

52. In 2004, Bard also investigated what was causing the Recovery Filter to fracture. Among other things, Bard believed that movement, whether tilting or migration of more than 2 cm, substantially increased the risk of fracture. Bard also determined that perforation of struts through the wall of the vena cava was causing fractures. Bard also discovered that tilt also led to the inability to retrieve the device and/or could lead to fractures during retrievals. Bard was aware that the diameter of the leg hooks is a substantial factor in a filter's ability resist migration and fatigue resistance.

53. By reducing the diameter of the hooks on the Recovery filter, Bard had reduced its ability to remain stable and not fracture.

54. Bard also reduced the leg span of the Recovery Filter from that of the Simon Nitinol filter by 25%, and as a result, knew that the device lacked a sufficient margin of safety to accommodate expansion of the vena cava (distension) after placement.

55. Bard was also aware that its failure to electropolish the wire material prior to distribution meant that the Device had surface damage that reduced its fatigue resistance.

56. Bard was also aware that the Recovery Filter had a high propensity to tilt and perforate the vena cava, which substantially increased the risk of fracture.

57. Bard was also aware that fatigue resistance could be increased by decreasing he sharpness of the angle of the wire struts where they exited the cap at the top of the Device, and by chamfering (rounding or reducing the sharpness) of the cap edge against which the struts rubbed.

58. A few examples of this knowledge and awareness include:

a. On June 18, 2003, BPV engineer, Robert Carr, sent an email noting that chamfering the edge of cap would reduce the likelihood of fracture.

b. On March 16, 2004, a BPV engineer sent an email admitting that the surface damage, as seen on the Recovery Filter from the manufacturing process, decreases fatigue resistance and that electropolishing increases fatigue resistance.

c. Drs. Venbrux's and Kaufman's warnings that the migration resistance of the Recovery Filter needed to be raised from 50 mmHg to 140 mmHg and that the device was "wimpy."

d. On May 5, 2004, a BPV engineer sent an email stating that adding a "chamfer" to filter will "address the arm fracture issue."

e. On May 26, 2004, a BPV engineer sent an email stating that a proposed modified Recovery Filter design with a large chamfer lasted 50 bending cycles before breaking, whereas another proposed modified Recovery Filter with a small chamfer broke after 10 bending cycles.

f. On December 27, 2005, Bard's Medical Affairs Director sent an email questioning why Bard is even selling the modified version of the Recovery Filter, when the Simon Nitinol Filter has virtually no complaints associated with it.

9. Bard Stopped Selling the Recovery Filter and Pushed the Bard G2 Filter into the Marketplace.

59. In or around April 2004, Bard, without notifying consumers of the design and manufacturing flaws inherent in the Recovery Filter, began redesigning the Recovery Filter in an attempt to correct its design flaws. The redesigned filter is known as the G2 Filter, which stands for second generation Recovery Filter.

60. Once Bard began marketing and selling the redesigned product in approximately August 2005, Bard quietly stopped selling the Recovery Filter. But, Bard continued to market the Recovery Filter as being safer and more effective than all prior filters up until the day the Recovery Filter was removed from the market. Moreover, Bard never issued a recall for the Recovery Filter, which had a three-year shelf life.

61. Instead of warning the public or withdrawing the device from the market, Bard retained a publicity firm and opened a task force to prevent information from getting out to the public, creating a Crisis Communication Team in 2004.

62. In an April 2004 email, BPV consultant Dr. Lehman, a member of the Crisis Communication Team, advised Bard to conceal material risk information from the public. Bard adopted his advice. In an email, Dr. Lehman wrote, "Comparison with other filters is problematic in many ways, and we should avoid/downplay this as much as possible. When pressed, we simply paraphrase what was said in the Health Hazard. That 'Estimates based on available data suggest that there is no significant difference in the rates of these complications between any of the devices currently marketed in the U.S., including the Recovery device.'" Dr. Lehman went on:

> I wouldn't raise this subject if at possible. It would be a most unusual reporter that will get this far. The testing data I saw in Arizona showed that although RF was certainly within the boundaries of devices tested, in larger veins it was near the bottom. I would avoid as much as possible getting into this subject, because I'm not sure others would agree with the conclusion that "Recovery Vena Cava Filter was Just as or more resistant to migration than all retrievable and non-retrievable competitors."

63. By December 2004, BPV's own safety procedure deemed the Recovery Filter not reasonably safe for human use. Bard continued to sell the Device into September of 2005.

C. THE G2 FILTER SYSTEM

64. On August 29, 2005, Bard obtained clearance to market the G2 Filter through the 510k process, representing to the FDA that the G2 Filter was substantially equivalent in respect to safety and efficacy as the Recovery Filter.

65. Bard asserted that the differences between the Recovery Filter and the G2 Filter were primarily dimensional and that it had made no material changes or added additional components. The G2 Filter was only cleared for permanent implantation until January 15, 2008. Thus, between September 2005 through all of 2007, Bard sold two filters, the Simon Nitinol Filter and G2 Filter, with the exact same indications for use.

66. Bard marketed the G2 Filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance" over all of its previous filters. Bard's marketing brochure states that supporting data was "on file." Yet, Bard refused to share this allegedly supporting evidence with consumers when it was asked for it. In reality, Bard knew or had reason to know these claims were false and misleading. Bard knew that the Simon Nitinol Filter was far less likely to fracture, migrate, tilt, or perforate the vena cava than the G2 or the Recovery Filter.

67. Further, Bard again failed to conduct adequate testing for long term safety and efficacy and failed to conduct adequate bench testing and animal studies to ensure that the device would perform safely and effectively once implanted in the human body and subjected to reasonably foreseeable in vivo stresses. Further, Bard still did not have a thorough and/or adequate understanding of vena caval dynamics. Not surprisingly, the G2 Filter's design still lacked adequate structural integrity, stability, and perforation resistance to withstand normal in vivo body stresses within the human without failing.

68. For instance, the new minimum safety migration resistance design requirement for the G2 Filter was that its migration resistance had to be "statistically greater" than that of the predicate Simon Nitinol Filter. Bard's testing established that the G2 Filter failed this requirement. However, instead of going back and modifying the device further to ensure this safety requirement was met, Bard changed the minimum safety requirement so that it just had to be better than the Recovery Filter.

69. Compounding this utter lack of concern for patient safety, Bard also decided that G2 filters could be reworked or reloaded on the jig used to form the filters up to five times in order to save money. Bard did this despite knowing that this would significantly decrease the migration resistance of such devices. To allow for this, Bard readopted the same minimum safety migration resistance specification that had been adopted and proven to be utterly unsupported for the Recovery Filter, *e.g.*, 50 mmHg.

70. Thus, knowing that the specification and migration resistance of the Recovery Filter had been inadequate and was resulting in patient death, Bard's premarket design requirement was that the device had to be at least as good as the Simon Nitinol Filter regarding migration resistance. When the G2 Filter failed that requirement, Bard simply changed the design requirement so that the G2 Filter just had to be at least as good as the device that it was known to be inadequate and causing patient deaths, the Recovery Filter.

71. The redesigned G2 Filter also still had substantially less radial force than did the Simon Nitinol Filter.

72. Bard again failed to account for how movement (tilt/migration), perforation, and fracture would affect device performance, despite knowing that these failures had occurred with the Recovery Filter.

73. Also, like its predecessor, in addition to design defects, the G2 Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the absence of electropolishing and the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2 Filter while in vivo. In particular, the G2 Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2 Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure and migration.

74. Within months of being released to market, post-market safety data revealed to Bard that the safety problems introduced with the Recovery Filter persisted. Some representative examples of this knowledge include the following:

a. Bard again received large numbers of adverse event reports reporting that properly placed G2 Filter were, *inter alia*, fracturing, migrating, tilting, and perforating the vena cava, often resulting in serious injuries and death.

b. By November 2005, Bard was aware of a "safety signal" regarding the high rate of reported perforation and movement failures.

c. In a December 25, 2005 email, Bard's Medical Director, Dr. David Ciavarella, questioned why Bard was even selling the G2 filter given the numerous reported failures when the Simon Nitinol Filter had virtually no reported adverse events.

d. By no later than February 2006, internal safety investigations revealed that the G2 Filter's design continued to fail to ensure adequate stability, as the device continued to tilt

and migrate at unreasonably high rates. Indeed, within months of being on the market, the G2 filter was found to migrate at rates that violated Bard's own safety threshold. The G2 Filter also exhibited a previously unseen failure: it would migrate downwards as well as upwards and side to side in the vena cava.

e. As with the Recovery Filter, Bard knew that movement, whether it be tilt or migration, increased the risk of fracture and strut perforation through the vena cava, as well as making the device irretrievable. For example, in a February 2006 Health Hazard Evaluation regarding G2 Failures, Bard's Medical Director acknowledged that tilt increases the risk of fracture and perforation and that events can cause serious injury and death. Similarly, a 2009 PowerPoint Presentation prepared by Bard's engineers, stated that movement causes tilt and that "tilted filter elements are more likely to penetrate IVC and adjacent structures due to change in the angle between the elements and the IVC." The PowerPoint states that tilting and perforation or penetration leads to fracture.

f. Bard's investigations into comparative failure risks between the different available devices continually showed that the G2 filters posed a substantially higher risk of migration, tilt, perforation and fracture.

g. By 2008, physicians were reporting that they believed there were fundamental design flaws with the G2 filter that was causing it to move, fracture, and perforate, and requesting evidence on the reported complication rates for the device. Bard's corporate policy was to refuse to disclose such failure rate data.

h. In a document dated April 1, 2010, senior Bard employees admitted that there were known quality problems with the G2 line of filters and redesigns (which includes the Eclipse), that Bard's own sales force had lost faith in the product, and that doctors were refusing

to use it. The document sets forth Bard's plan to reduce the risk of tiling, perforation, fracture, and migration by improving the anchoring system on the G2 line of filters. This became the Meridian filter, which was cleared through the 510(k) process on October 24, 2011.

i. Recent medical studies report that the G2 will suffer a 38 to 40 percent fracture rate at four to five years.

75. As with the Recovery Filter, these failures often caused severe patient injuries such as:

a. death;

b. hemorrhage;

c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. severe and persistent pain; and

f. perforations of tissue, vessels and organs.

76. Despite being aware from February 2006 that the G2 Filter was not safe for its intended use and was substantially more likely to fail and cause patient injuries than all other available IVC Filters devices, Bard continued to sell the device into 2010 and even continued to market it as safer than Bard's permanent filter, the Simon Nitinol Filter.

D. THE ECLIPSE FILTER

77. Bard's Eclipse IVC filter was released onto the market in 2010 while the G2 was still on the market. This was a modification of the Recovery and G2 filters. Each design of Bard's retrievable filter following Recovery relied on the predecessors as the predicate device. The

Eclipse is almost identical in design to the G2 except it was electropolished. It is essentially part of the G2 line of filters.

78. According to Bard's internal testing, electropolishing supposedly increased fracture resistance by 25% and therefore was purportedly a safer alternative to the Recovery and G2 Filter product line.

79. However, Longitudinal Studies published in peer-reviewed medical literature found that among 363 patients implanted with the Recovery Filter and 658 patients implanted with the G2 Filter, the devices experienced fracture rate of 40% and 37.5%, respectively, after five and a half years.

80. Thus, even if the Eclipse truly was a safer alternative to the Recovery and G2 Filters as Bard claimed, an enormous percentage (approximately 28.125% to 30%) of Eclipse Filters would still be projected to fracture within five and a half years.

81. Without meaningful design changes, the Eclipse Filter continued to share several of the same design defects and complications associated with the Recovery Filter and G2 family of filters.

82. Soon after Bard launched the Eclipse Filter, it began receiving complaints and reports of injuries associated with the Eclipse Filter similar to those received with its predecessor filters.

83. Bard, however, knew and/or soon learned that the Eclipse Filter was not the substantial equivalent of the SNF, making this device also misbranded and adulterated, and subjected to recall.

84. In 2010, the same year as the Eclipse was released onto the market, the FDA issued a warning regarding reports of increasing adverse events associated with IVC Filters as well as

very low rates of retrieval. This included a recommendation that the filters be removed if once protections from PE was no longer needed.

85. In 2014, the FDA further renewed this advisory and had recommendations for the length of time a filter should remain in a patient (optimal retrieval window was between 29 and 54 days) and the need to remove the filter if it was no longer clinically indicated.

86. Bard knew when it designed and sold Eclipse filters that they would often be utilized as permanent filters. Bard knew that research showed the longer the filters remained in the patients, the greater risk there was for adverse events.

87. Bard knew when it designed and sold Eclipse filters that once the filters were implanted, most patients would never see the implanting doctor again and instead would then be followed by their family doctors or other doctors. Yet, all of these doctors were not informed by Bard that the filters could silently perforate, migrate, fracture or cause other adverse events greater than in other filters.

88. Despite these FDA warnings and knowledge of increased adverse events, Bard never communicated these warnings to the doctors implanting and/or doctors treating patients with these filters.

89. Despite these FDA warnings and knowledge of increased adverse events, Bard never initiated a medical monitoring program to help doctors monitor these filters and discover adverse events.

90. Bard had an on-going requirement by the FDA to conduct post-sale reporting and surveillance of adverse events. Bard did not fully comply but instead mischaracterized some adverse experiences as not being serious. This included perforations, migrations, difficulty with

removal, embolization, tilt, DVT and even fractures of the Recovery, G2 and Eclipse and successor designs.

91. Despite its knowledge of increased adverse events with its filters, Bard did not study the Eclipse in people before it was released for sale on the market to determine if it perforated, migrated or fractured more than other filters. In 2012 a study was published that confirmed that Bard's filters had higher rates of fracture (12%) and embolization (13%). Once the IVC failed, removal was more difficult. Additionally, only half the patients in the study were able to have fractured components successfully removed.

92. Bard knew when it designed and sold the Eclipse filter (and any other of its retrievable IVC filters) that the efficacy of the IVC filter to prevent deadly pulmonary embolisms was unproven in human trials. Bard knew there is a limited body of evidence-based literature to support the high utilization of IVC filters. The only randomized study, PREPIC 1, showed limited protection from symptomatic recurrent PE but with an increased risk of DVT and no long term survival benefit. Since the Eclipse has been sold, several published studies, including PREPIC 2, have shown that IVC filters do not reduce the risk of PE or mortality and increase the risks of DVT. In short, Bard knew and has continued to know there was a lack of evidence to support IVC use yet they withheld information from doctors and patients about the increased risks of the device, the difficulty in removing the device and the lack of evidence of efficacy. If the device has little or no efficacy but increases the risks of adverse events, then the risks of the device far outweigh the benefits.

E. FDA WARNING LETTER

93. On July 13, 2015, the FDA issued a Warning Letter to Bard notifying that its IVC Filters were adulterated and misbranded under federal law.

94. The FDA notified Bard that its IVC Filters were adulterated and misbranded because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Section 820.

95. The FDA also notified Bard that it had failed to comply with adverse event reporting requirements of 21 C.F.R. 803.

96. The FDA cited numerous specific violations, including the failure to establish and maintain procedures to ensure that product complaints are adequately investigated and reported, and a consistent pattern of Bard underreporting the severity of injuries caused by device failures and failing to report device malfunctions all together.

97. For instance, the FDA cited numerous examples of Bard reporting G2, Eclipse and other IVC filter failures resulting in deaths and other serious injuries as if there was no patient injury involved. The FDA also found that Bard had failed to establish and maintain a procedure to ensure that the toxic acids and chemicals used in the manufacture of its filters were reduced to acceptable levels prior to distribution.

98. Shortly thereafter, the FDA required Bard and other filter manufacturers to demonstrate the safety of its filters. In 2015 Bard and other manufacturers engaged in a single arm study with a target enrollment of 2,100 patients known as PRESERVE. Patients are being monitored at 3 months, 6 months, 12 months, 18 months and 24 months after filter placement. Monitoring includes CT scans. While this study will not determine efficacy, this type of study regarding adverse events should have been performed before the G2 filter was sold. As of the filing

of this Complaint, more than 5 years later, no results of the PRESERVE study have been released to the public.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

99. On November 2, 2004, Plaintiff Peter G. Krauss received a Bard Recovery filter during an implantation procedure performed by Dr. Michael Medvecky at Yale-New Haven Hospital in New Haven, Rhode Island.

100. On May 2, 2019, Plaintiff underwent a complex procedure to remove his Bard Recovery IVC filter at Stanford Hospital in Stanford, California. Drs. William Kuo and Roger Goldman performed Plaintiff's complex filter removal procedure.

101. Drs. Kuo and Goldman performed the removal procedure percutaneously with a complex technique using endobronchial forceps after the client had experienced intermittent back pain and "stabbing" stomach pain.

102. During the removal procedure, Drs. Kuo and Goldman noted that Plaintiff's Bard Recovery IVC filter had become chronically embedded.

103. Due to the embedded nature of Plaintiff's IVC filter, Drs. Kuo and Goldman noted that the removal procedure required substantial additional physical and mental effort.

104. Further, upon inspection of Plaintiff's Bard Recovery IVC filter after the retrieval, Drs. Kuo and Goldman noted that the IVC filter device had a fractured filter strut that had been retained inside Plaintiff and which had not been recovered during the removal procedure.

105. Plaintiff first learned of his injuries caused by his IVC Filter when he discussed the results of his IVC filter removal procedure with his doctors on May 2, 2019. Prior to this removal procedure, Plaintiff had no way of knowing of the injuries caused by his IVC filter.

106. Following the removal procedure, Dr. Kuo informed Plaintiff that his embedded filter was one of the worst filter removal cases that Dr. Kuo had encountered.

107. As a consequence of his removal surgery, many daily life activities became more difficult and caused Plaintiff to suffer a great deal of pain and suffering.

FIRST CLAIM FOR RELIEF:
NEGLIGENCE

108. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

109. At all times relevant to this cause of action, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Device.

110. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Device that was implanted in Plaintiff.

111. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Device and to timely withdraw/remove/recall these filters from the market so as to avoid exposing others to foreseeable and unreasonable risks of harm.

112. Defendants knew or had reason to know that the Device was dangerous or were likely to be dangerous when used in its intended or reasonably foreseeable manner.

113. At the time of manufacture and sale of the Device, Defendants knew or should have known that the Device was:

a. defectively designed and manufactured so as to present a unreasonable risk of the Device perforating the vena cava wall;

b. defectively designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the Device;

c. defectively designed and manufactured so as to present a unreasonable risk of migration of the Device and/or portions of the Device;

d. defectively designed and manufactured so as to present a unreasonable risk of the Device tilting in the vena cava wall;

e. defectively designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and

f. defectively designed and manufactured so as to present a unreasonable risk in that the Device cannot be removed, cannot be removed utilizing a minimally invasive percutaneous technique and/or can only be removed through an open vascular surgical procedure.

114. At the time of manufacture and sale of the Device, Defendants knew or should have known that the Device in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the Device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

115. Defendants knew or reasonably should have known that consumers of the Device would not realize the danger associated with using the Device in its intended use and/or in a reasonably foreseeable manner.

116. Defendants breached their to duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Device in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiff, Plaintiff's physicians, or the general health care community about the Device's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre and post-market testing of the Device to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Device;

g. Advertising, marketing and recommending the use of the Device while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the Device;

h. Representing that the Device was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Device with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with the good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Device so as to avoid the risk of serious harm associated with the use;

k. Advertising, marketing, promoting and selling the Device for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Device; and,\

m. Failing to establish and maintain and adequate post-market surveillance program.

117. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

118. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional

medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that Plaintiff's injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

SECOND CLAIM FOR RELIEF:
NEGLIGENT FAILURE TO WARN

119. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

120. At all times relevant to this cause of action, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Device.

121. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Device that was implanted in Plaintiff.

122. Defendants had a duty to exercise reasonable and prudent care to give appropriate warnings about particular risks of the Device which Defendants knew or should have known are in involved in the reasonably foreseeable uses of the Device.

123. Defendants knew or reasonably should have known that the Device was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

a. At the time of manufacture and sale of the Device, Defendants knew or should have known that the Device:

b. Was defectively designed and manufactured so as to present a unreasonable risk of the Device perforating the vena cava wall;

c. Was defectively designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the Device;

d. Was defectively designed and manufactured so as to present a unreasonable risk of migration of the Device and/or portions of the Device;

e. Was defectively designed and manufactured so as to present a unreasonable risk of the Device tilting in the vena cava wall;

f. Was defectively designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and.

g. Was defectively designed and manufactured so as to present a unreasonable risk in that the Device cannot be removed, cannot be removed utilizing a minimally invasive percutaneous technique and/or can only be removed through an open vascular surgical procedure.

124. At the time of manufacture and sale of the Device, Defendants knew or should have known that using the Device in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the Device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

125. Defendants knew or reasonably should have known that consumers of the Device would not realize the danger associated with using the Device in its intended use and/or in a reasonably foreseeable manner.

126. Defendants breached their to duty to exercise reasonable and prudent care in failing to give appropriate warnings about the particular risks of the Device and further failed to disclose that the safety profile of the Device was worse than competitor filters.

127. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

128. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that Plaintiff's injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF:
STRICT LIABILITY FAILURE TO WARN

129. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

130. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold IVC filters such as the Device, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the Device to consumers or persons responsible for consumers.

131. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Device into the stream of commerce, Defendants knew or should have known the Device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically,

Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the Device, which was implanted in Plaintiff, that the Device, *inter alia*, posed a significant and higher risk than other similar devices of failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries.

132. Defendants had a duty to warn of the risk of harm associated with the use of the Device and to provide adequate instructions on the safe and proper use of the Device.

133. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the Device was distributed and implanted in Plaintiff.

134. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Device, and further failed to adequately provide instructions on the safe and proper use of the Device. Furthermore, the foreseeable risks of harm from the Device could have been reduced or avoided by providing reasonable instructions and/or warnings and the failure to provide those instructions or warnings makes the Device unreasonably dangerous and renders the Device defective.

135. No health care provider, including Plaintiff's, or patient would have used the Device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the Device.

136. The health risks associated with the Device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

137. Plaintiff and Plaintiff's health care providers used the Device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted Device used to prevent pulmonary emboli.

138. The Device implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

139. The Device implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

140. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that Plaintiff's injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

FOURTH CLAIM FOR RELIEF:
STRICT LIABILITY DESIGN DEFECT

141. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

142. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the Device, including the one implanted in Plaintiff.

143. The Device was in a condition unreasonably dangerous and was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession, or with changes that were reasonably foreseeable to Defendants.

144. The Device implanted in Plaintiff was defective in design because it failed to perform as safely as an ordinary consumer would expect when used as intended or when uses in a manner reasonably foreseeable by Bard and/or the risk of danger in the design outweighed the benefits of the filter.

145. The Device implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

146. Plaintiff and Plaintiff's health care providers used the Device in a manner that was reasonably foreseeable to Defendants.

147. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of reasonable care discovered the Device's defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the Device.

148. As a direct and proximate result of the Device's defective design, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that Plaintiff's injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

FIFTH CLAIM FOR RELIEF:
STRICT LIABILITY MANUFACTURING DEFECT

149. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

150. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Device that was implanted into

Plaintiff. The Device was unreasonably dangerous at the time it left Defendants' control because of a manufacturing defect, i.e., it was different from its intended design and failed to perform as safely as the intended design would have performed.

151. The Device implanted in Plaintiff was in a condition unreasonably dangerous and the filter was expected to and did reach Plaintiff and/or Plaintiff's physicians without substantial change affecting that condition.

152. Plaintiff and Plaintiff's health care providers used the Device in a manner that was reasonably foreseeable to Defendants.

153. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

154. As a direct and proximate result of the Device's manufacturing defect, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that Plaintiff's injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

SIXTH CLAIM FOR RELIEF:
BREACH OF EXPRESS WARRANTY

155. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

156. Through sales representatives, consultants, printed materials and other advertising and marketing efforts, Defendants made express representations to healthcare providers and

patients, including Plaintiff and Plaintiff's healthcare providers, about the safety and efficacy of the Device.

157. Plaintiff and Plaintiff's healthcare providers relied upon the aforementioned express representations made by Defendants in deciding to purchase and implant the Device.

158. The Device does not conform to the express representations of fact made by Defendants through sales representatives, consultants, printed materials, and other advertising and marketing efforts and Plaintiff and/or Plaintiff's physicians relied on these express representations in the purchase, use and implantation of the Device in Plaintiff.

159. The Device's failure to conform to the foregoing express representations made by Defendants caused Plaintiff's injuries.

SEVENTH CLAIM FOR RELIEF:
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

160. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

161. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce IVC filters such as the Device for use as a surgically implanted Device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

162. At the time and place of the sale, distribution, and supply of Defendants' Device to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the Device was safe and effective for its intended and reasonably foreseeable use.

163. Defendants knew of the intended and reasonably foreseeable use of the Device, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

164. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the Device was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

165. Plaintiff and Plaintiff's healthcare providers relied upon the aforementioned implied representations made by Defendants in deciding to purchase and implant the Device.

166. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the Device was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the Device from Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and

c. It was manufactured in such a manner so that the exterior surface of the Device was inadequately, improperly and inappropriately prepared and/or finished causing the Device to weaken and fail.

167. Plaintiff and Plaintiff's health care providers acted reasonably in relying on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the

product, as to whether the Device was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Device were manufactured and sold.

168. Defendants placed the Device into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the Device was manufactured and sold.

169. Defendants breached their implied warranty because the Device is not fit for its intended use(s) and/or the use(s) reasonably foreseeably by the Defendant.

170. As a proximate result of Defendants' breaching their implied warranties, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that Plaintiff's injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

EIGHTH CLAIM FOR RELIEF: BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

171. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

172. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the Device for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

173. At the time and place of the sale, distribution, and supply of Defendants' Device to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the Device was safe and effective for its intended and reasonably foreseeable use.

174. Defendants knew of the intended and reasonably foreseeable use of the Device, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

175. Defendants knowingly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the Device was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

176. Plaintiff and Plaintiff's healthcare providers relied upon the aforementioned implied representations made by Defendants in deciding to purchase and implant the Device.

177. The representations and warranties made by Defendants were false, misleading, and inaccurate because the Device was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the Device from Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and

c. It was manufactured in such a manner so that the exterior surface of the Device was inadequately, improperly and inappropriately prepared and/or finished causing the Device to weaken and fail.

178. Plaintiff and Plaintiff's health care providers acted reasonably in relying on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether the Device was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Device was manufactured and sold.

179. Defendants placed the Device into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the Device was expected to and did reach Plaintiff without substantial change in the condition in which the Device was manufactured and sold.

180. Defendants breached their warranty of fitness for a particular purpose because the Device is not fit for the specific purpose for which the Defendant's knowingly sold it and for which, in reliance on the judgment of the Defendant's, Plaintiff and/or Plaintiff's physicians bought and implanted the Device.

181. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer significant medical expenses, extreme pain and suffering, mental anguish, loss of enjoyment of life, disability, and other losses proximately caused by the Device. Plaintiff will have continued risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor Plaintiff's health to ensure that Plaintiff's injuries caused by the Device do not cause additional or further injury, in an amount to be determined at trial.

NINTH CLAIM FOR RELIEF:
FRAUDULENT CONCEALMENT

182. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

183. Defendants were and are under a continuing duty to disclose the true character, quality and nature of the Device that was implanted in Plaintiff, but instead they concealed them, thus breaching this duty.

184. At all times relevant to this cause, Defendants fraudulently concealed material information concerning the Device from Plaintiff, Plaintiff's health care providers, and the general medical community relating to the safety of the Device, the efficacy the Device and the rate of failure of the Device.

185. Defendants concealed the applicable facts intentionally in order to defraud or mislead Plaintiff.

186. Plaintiff and Plaintiff's healthcare providers reasonably relied on Defendants' omission to state that the true character, quality and nature of the Device was far worse than promised in deciding to purchase and implant the Device.

187. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of Plaintiff's claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing these causes of action. Defendants' fraudulent concealment did result in such delay.

188. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Device.

189. Plaintiff and Plaintiff's health care providers could not reasonably have discovered the claims made herein until at the earliest May 2, 2019, when the Device was first suspected to have injured Plaintiff.

190. Defendants' conduct, as described in this Complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

TENTH CLAIM FOR RELIEF:
NEGLIGENT MISREPRESENTATION

191. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

192. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false, misleading or incorrect information, or omitted or failed to disclose material information/facts/facts concerning the Device that the Defendant's knew or should have known was in fact false and misleading, Defendants' made these false and misleading statements intending that the statements would be relied on by Plaintiff, Plaintiff's health care providers and the general medical community and Plaintiff and Plaintiff's health care providers justifiably relied upon the Defendant's false and misleading statements. The Defendant's false and misleading statements concerned the following material facts and subjects:

a. The safety of the Device;

b. The efficacy of the Device;

c. The rates of failure of the Device; and

d. The approved uses of the Device.

193. The false and misleading information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Device. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the Device that was implanted in Plaintiff.

194. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Device and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Device.

195. The foregoing representations and omissions by Defendants were in fact false. The Device is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of IVC filters like the Device is hazardous to the user's health, and said Device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the Device has a significantly higher rate of failure and injury than do other comparable devices. In reliance upon the false and negligent misrepresentations and

omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the Device, thereby causing Plaintiff to sustain severe and permanent personal injuries.

196. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the Device had not been concealed and misrepresented by Defendants.

197. Defendants were and are under a duty to impart correct information to Plaintiff and Plaintiff's healthcare providers.

198. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Device.

199. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Device, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

200. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Device.

201. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' was the direct and proximate cause of Plaintiff's injuries as described herein.

ELEVENTH CLAIM FOR RELIEF:
FRAUDULENT MISREPRESENTATION

202. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

203. At all times relevant to this cause, Defendants intentionally made false statements of material fact to Plaintiff, Plaintiff's health care providers, and the general medical community or intentionally omitted or intentionally failed to disclose material information concerning the Device knowing that such statements and omissions were in fact false and misleading or without concern for whether the statements or omissions were true or false.

204. Defendants made these false and misleading statements intending that the statements would be relied on by Plaintiff, Plaintiff's health care providers and the general medical community and Plaintiff and Plaintiff's health care providers relied upon the Defendant's false and misleading statements. The Defendant's false and misleading statements concerned the following material facts and subjects:

a. The safety of the Device;

b. The efficacy of the Device;

c. The rates of failure of the Device; and

d. The approved uses of the Device.

205. The false and misleading information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Device. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials

included instructions for use and warning document that was included in the package of the Device that was implanted in Plaintiff.

206. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Device and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Device.

207. The foregoing representations and omissions by Defendants were in fact false. The Device is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Device is hazardous to the user's health, and said Device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the Device has a significantly higher rate of failure and injury than do other comparable devices.

208. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did, use the Device, thereby causing Plaintiff to sustain severe and permanent personal injuries.

209. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the Device had not been concealed and misrepresented by Defendants.

210. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Device.

211. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Device, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

212. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Device.

213. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' was the direct and proximate cause of Plaintiff's injuries as described herein.

214. These acts by Bard were also unfair and deceptive and proximately caused Plaintiff's injuries in violation of North Carolina's Consumer Fraud Statute N.C. Gen. Stat. Section 75-1(a).

TWELFTH CLAIM FOR RELIEF: PUNITIVE DAMAGES ALLEGATIONS

215. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

216. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard and indifference for the public safety and welfare.

217. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Device was defective and unreasonably dangerous, had a substantially higher failure rate than did other similar devices on the market and had a lack of evidence of efficacy. Yet, Defendants failed to:

a. Inform or warn Plaintiff or Plaintiff's health care providers of the dangers;

b. To establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the Device from the market.

221. Defendants acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

222. Defendants' actions were malicious, willful, wanton and reckless. Defendants' conduct were not motivated by an interest in manufacturing and selling a safe and better medical product, but rather to take over the market, squeeze out the competition, so that profits would increase significantly.

223. Defendants' conduct was directed by its Board of Directors and CEO. Defendants acted through their agents to increase the Bard market share, without regard for the safety and efficacy of its devices.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues which may be tried by a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court order Defendants to provide the following relief:

1. All applicable damages, including:

a. General and consequential damages, including pain and suffering, mental anguish, loss of enjoyment of life, disability, scarring and disfigurement, risk of requiring additional medical care and surgical procedures, ongoing medical monitoring, and other losses proximately caused by the Device according to proof at trial;

b. Medical and other special damages, past, present, and future, according to proof at the time of trial;

2. Punitive damages;

3. Costs of suit, including payment of experts' fees and expenses;

4. Reasonable attorneys' fees;

5. Prejudgment and post judgment interest as provided by law; and,

6. Such other and further relief as the Court may deem just and proper.

Dated: February 17, 2021

Respectfully submitted,

By: /s/ Vincent L. Greene

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